## REMARKS

Claims 16, 23 and 24 have been amended. No new matter has been added by virtue of the amendment. Support therefor can be found throughout the specification and in the original claims.

As an initial matter, Applicants appreciate the indication of allowable subject matter, i.e., that claims 16-22 are allowable over the prior art of record.

Applicants also wish to thank Examiner Padmanabhan and Supervisory Examiner Le for their helpful comments during a personal interview conducted on January 6, 2004, with Applicants' representative, Dr. Raj Bawa. As an interview summary was already prepared and issued by Examiner Padmanabhan, no further summary is provided herein.

Referring now to the Office Action, it is indicated that the Information Disclosure Statement filed on July 17, 2003, failed to comply with 37 CFR 1.98 (a)(3). Consequently, the Office Action indicates that one of the documents cited, JP 5-500007, was not considered as it did not include a concise explanation of its relevance.

Applicants note that JP 5-500007 corresponds to WO 91/02080 that also was listed in the Supplemental IDS submitted on July 17, 2003. Namely, the noted Japanese document is the publication of Japanese national phase application of the PCT application published as WO 91/02080. Hence, JP 5-500007 corresponds directly to WO 91/02080. Since the initialed FORM PTO-1449 returned with the present Office Action indicates that WO 91/02080 has been considered, Applicants respectfully request that the PTO-1449 be reissued to indicate that the Japanese document has been duly considered.

Claims 16-24 are rejected under 35 USC §112, 2nd paragraph. The Office Action alleges that recitation of "an antibody concentration greater than 0.01μg/ml" renders the claim indefinite because an upper bound of concentration has not been included.

Applicants submit that the claim is abundantly clear when read in view of the supporting specification, as is proper. In particular, rejected claim 16 clearly indicates that the antibody concentration must be at least 0.01μg/ml or more. The skilled artisan would readily understand the meaning of the phrase and there is nothing indefinite or vague about its meaning. Additionally, the specification provides clear guidance as to what concentrations or dilutions of the antibody can be employed. In particular, attention is directed to page 26, lines 16-20 of the present application.

The test for definiteness under 35 U.S.C. §112, 2nd paragraph is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). In this regard the MPEP 2173.03 clearly states:

> Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

While Applicants disagree with the instant rejection, it also is believed to be obviated in view of the within amendments and the discussion which took place during the recent personal interview. In particular, the allegedly indefinite language has been stricken from claim 16 and the claim has been further amended to include recitation of *an effective amount* of the anti-acetylated peptide antibody which recognizes *with specificity* only an acetylated form of the peptide substrate and which does not recognize the peptide substrate in its unacetylated form.

Referring to the Interview Summary (PTOL-413) issued on January 6, 2004, it was indicated that such amendments were discussed as overcoming the outstanding 112, 2nd paragraph rejection issues. In particular, it was emphasized during the interview that the antibody concentration was not a critical feature to the present invention. Indeed, the minimum and maximum antibody binding concentrations vary with the specific technique employed to detect and measure them. One of ordinary skill would readily understand the meaning of the presently recited language. The phrase "effective amount" as recited in amended claim 16 is indeed definite; support for this phrase is present at page 26 of the specification where ELISA was used to measure/detect the anti-acetylated peptide antibody with specificity. Clearly, one of ordinary skill in the art would be able to determine what is implied by the phrase "effective amount" in the context recited in claim 16. Additionally, MPEP 2173.05(c) states:

> The common phrase "an effective amount" may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an "effective amount of a compound of claim 1" without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected.

Withdrawal of the rejection is therefore requested.

Claims 23-24 stand rejected under 35 U.S.C. §103 over Lill et al. (*Nature*, 1997).

Claims 23-24 stand rejected under 35 U.S.C. §103 over Gu et al. (*Cell*, 1997).

The rejection is traversed.

The cited references, whether considered alone or even in combination, do not teach or suggest the methods of the present invention.

For instance, both Lill et al. and Gu et al. disclose a p300 acetyltransferase which binds to the p53 substrate. Lill et al. disclose how the binding can be inhibited via E1A. Gu et al. disclose how the binding can be activated via a monoclonal antibody directed to p53. Although the cited art lacks any disclosure of a kit *per se* or deacetylase, the position is taken that it would be obvious to package the various components of the cited art and additionally incorporate a deacetylase in order to arrive at the Applicants' kit.

Obviousness can only be established by modifying (or combining) the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art [See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992)].

Applicants respectfully submit that there would be no motivation to incorporate a deacetylase into Applicants kit arrangement in view of the cited prior art. Further, the cited art is indeed silent as to any kit or screening method of any kind. Thus, there would be no motivation to modify the cited art, nor would there be any reasonable expectation of success. In this case, the kits of claims 23-24 appear to have been improperly considered using hindsight reconstruction as a series of components rather than as a whole invention.

In any case, in an effort to overcome the rejection and expedite allowance of the application, claims 23-24 have been further amended in parallel to claim 16 (which claim is believed to be allowable in its present form based on the Interview Summary of January 6, 2004). The subject matter of claims 23-24 is neither disclosed nor suggested by the prior art cited. In view of the above discussion and the within amendments, it is submitted that the amended claims 23-24 are clearly not obvious under 35 USC§ 103(a) over Lill et al. or Gu et al.. Withdrawal of the rejection is therefore requested.

It is believed the application is in condition for immediate allowance, which action is earnestly solicited.

Respectfully submitted,

Christine C. O'Day (Reg. 38,256)
EDWARDS & ANGELL, LLP
P.O. Box 55874
Boston, MA 02205

Tel. (617) 439-4444